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10/598,536	09/01/2006	Shigeru Nemoto	KITO15.001APC	6996

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
02/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,536	NEMOTO ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/5/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Tachibana (US 2005/0029277). Tachibana discloses a chemical liquid injection system (Figs. 1-10) including: a liquid syringe (Figs. 2b and 3, syringe is 2) having a piston member (Fig. 2b, 2p) being inserted slidably into a cylinder member filled with a liquid, and a chemical liquid injector (50) having a liquid injection mechanism (52) for relatively moving the cylinder member and the piston member of the liquid syringe exchangeably mounted on the chemical liquid injector to inject the liquid into a patient; wherein said liquid syringe further comprises an RFID chip (3) having various types of data including identification data for said liquid syringe recorded thereon (paragraph [0048] discloses that multiple types of data regarding the liquid in the syringe is recorded on the tag), the RFID chip being mounted on said liquid syringe (Figs. 2b and 3), and said chemical liquid injector further comprises: an RFID reader (Fig. 3, 101) for obtaining the various types of data recorded on the RFID chip; and operation control means for performing a

predetermined operation in accordance with at least some of the various types of obtained data (paragraphs [0056]-[0058]), and wherein said operation control means comprises data storing means for storing predetermined check conditions including identification data of usable liquid syringe (Fig. 3, 102; paragraph [0055] discloses that information is read from the tag on the syringe and then this information is stored in 102 such that it can be recalled and compared), data collating means for collating the stored check conditions with the various types of data obtained from said RFID chip (paragraphs [0056] and [0057] disclose that the data is compared by some sort of comparator in order to determine whether an alarm needs to be triggered), data accumulating means for storing the identification data (102; paragraph [0056] discloses that the data is stored so that it can be compared to a set value, which also must be stored in order for it to be compared), and alarm outputting means for outputting a check alarm if the identification data obtained from said RFID chip is not included in the check conditions as a result of the collation (paragraphs [0056] and [0057] disclose that if the data is determined to be out of range, the buzzer alarm is triggered). In reference to claims 2-9 and 12-14 see Figs. 1-10 and paragraphs [0048] and [0056]-[0058].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana (US 2005/0029277) in view of Wilson et al. (US Patent No. 5,573,515). Tachibana discloses the device substantially as claimed except for a liquid warmer in associated with the injector. Wilson, however, discloses a similar chemical liquid injection system (Fig. 1, for example) as well as a heater to heat the liquid in the syringe (col. 8, lines 17-27). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tachibana with the liquid heater to heat the contents of the syringe, as taught by Wilson, in order to provide a device that will administer liquids to patients that are close to body temperature to ensure that the patient is more comfortable.

Claims 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana (US 2005/0029277) in view of Hickle et al. (US 2003/0074223). Tachibana discloses the device substantially as claimed including: a chemical liquid injection

system (Figs. 1-10) including: a liquid syringe (Figs. 2b and 3, syringe is 2) having a piston member (Fig. 2b, 2p) being inserted slidably into a cylinder member filled with a liquid, and a chemical liquid injector (50) having a liquid injection mechanism (52) for relatively moving the cylinder member and the piston member of the liquid syringe exchangeably mounted on the chemical liquid injector to inject the liquid into a patient; wherein said liquid syringe further comprises an RFID chip (3) having various types of data including identification data for said liquid syringe recorded thereon (paragraph [0048] discloses that multiple types of data regarding the liquid in the syringe is recorded on the tag), the RFID chip being mounted on said liquid syringe (Figs. 2b and 3), and said chemical liquid injector further comprises: an RFID reader (Fig. 3, 101) for obtaining the various types of data recorded on the RFID chip; and operation control means for performing a predetermined operation in accordance with at least some of the various types of obtained data (paragraphs [0056]-[0058]), and wherein said operation control means comprises data storing means for storing predetermined check conditions including identification data of usable liquid syringe (Fig. 3, 102; paragraph [0055] discloses that information is read from the tag on the syringe and then this information is stored in 102 such that it can be recalled and compared), data collating means for collating the stored check conditions with the various types of data obtained from said RFID chip (paragraphs [0056] and [0057] disclose that the data is compared by some sort of comparator in order to determine whether an alarm needs to be triggered), data accumulating means for storing the identification data (102; paragraph [0056] discloses that the data is stored so that it can be compared to a set value, which

also must be stored in order for it to be compared), and alarm outputting means for outputting a check alarm if the identification data obtained from said RFID chip is not included in the check conditions as a result of the collation (paragraphs [0056] and [0057] disclose that if the data is determined to be out of range, the buzzer alarm is triggered).

Tachibana, however, does not disclose that the data included in the RFID chip includes the expiration date of the liquid in the syringe, or that the predetermined check conditions include the current date and time. Hickle, however, discloses a similar device which delivers medication and the medication container (a vial) includes an RFID chip on it (paragraph [0046]) which includes data about the fluid filled container such as the expiration date (paragraph [0028]). Hickle further discloses that the device keeps track of the current date and time so that if the reader reads the RFID chip and it says that the drug is expired, the drug will not be delivered and an alarm will be triggered (paragraphs [0030] and [0038] and [0039]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tachibana's RFID chip so that the expiration date of the drug is included and modified the device of Tachibana so that the current date and time are kept track of, so that a safer device is provided and an expired drug is not accidentally administered to the patient which in worst case scenarios could kill the patient. In reference to claims 19-31, see Figs. 1-10 and paragraphs [0048] and [0056]-[0058].

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tachibana (US 2005/0029277) in view of Hickle et al. (US 2003/0074223) and further in view of Wilson et al. (US Patent No. 5,573,515). Tachibana in view of Hickle discloses the device substantially as claimed except for a liquid warmer in associated with the injector. Wilson, however, discloses a similar chemical liquid injection system (Fig. 1, for example) as well as a heater to heat the liquid in the syringe (col. 8, lines 17-27). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tachibana in view of Hickle with the liquid heater to heat the contents of the syringe, as taught by Wilson, in order to provide a device that will administer liquids to patients that are close to body temperature to ensure that the patient is more comfortable.

Response to Arguments

Applicant's arguments with respect to claims 1-9, 12-31 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767